

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SCOTT M. EPSTEIN,

Plaintiff,

v.

C.R. BARD, INC., *et al.*,

Defendants.

Civil Action No. 03 CV 12297 (RWZ)

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U.S. DISTRICT COURT
DISTRICT OF MASS.

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT C.R. BARD, INC.'S
MOTION TO DISMISS COUNTS II, III, IV, V, VI, VII, VIII AND X OF PLAINTIFF'S
COMPLAINT**

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INTRODUCTION

Counts II, III, IV, V, VI, VII, VIII and X of Plaintiff's Complaint should be dismissed.

Each of the eight claims should be dismissed for failure to state a claim against C. R. Bard, Inc. ("Bard") upon which relief can be granted. This is true because the Complaint and documents incorporated therein leave no doubt that each claim is time-barred. In addition, several of the eight claims should be dismissed for other fatal deficiencies – namely, failure to plead fraud with particularity and failure to plead facts with respect to each material element of a given claim.

Moreover, three of Plaintiff's claims should be dismissed for lack of subject matter jurisdiction. This is true because, to the extent Plaintiff advances a "fraud-on-the-FDA" theory of recovery, his three fraud-based claims are impliedly pre-empted by federal law.

ARGUMENT

I. Each Of The Eight Counts Fails To State A Claim Upon Which Relief Can Be Granted

A. Relevant 12(b)(6) Standards

A complaint should be dismissed for failure to state a claim where "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-6 (1957). *See also Rockwell v. Cape Cod Hosp.*, 26 F.3d 254, 255 (1st Cir. 1994).

In deciding a 12(b)(6) motion, the court will "treat all allegations in the complaint as true and draw all reasonable inferences therefrom in favor of the plaintiff." *Rumford Pharmacy, Inc. v. East Providence*, 970 F.2d 996, 997 (1st Cir. 1992). However, a court is not "obliged ... to 'credit bald assertions, periphrastic circumlocutions, unsubstantiated conclusions, or outright vituperation[.]'" *United States v. AVX Corp.*, 962 F.2d 108, 115 (1st Cir. 1992) (quoting *Correa-*

Martinez v. Arrillaga-Belendez, 903 F.2d 49, 52 (1st Cir. 1990)). Neither must it “‘honor subjective characterizations, optimistic predictions, or problematic suppositions.’ ‘Empirically unverifiable’ conclusions, not ‘logically compelled, or at least supported, by the stated facts,’ deserve no deference.” *AVX Corp.*, 962 F.2d at 115 (quoting *Dartmouth Review v. Dartmouth College*, 889 F.2d 13, 16 (1st Cir. 1989)).

That is, in the First Circuit, the notice pleading requirement “is not entirely a toothless tiger.” *Dartmouth Review*, 889 F.2d 13 at 16. “The threshold [for stating a claim] may be low, but it is real.” *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 514 (1st Cir. 1988) (affirming 12(b)(6) dismissal by Zobel, J. of complaint alleging, *inter alia*, breach of contract and violation of M.G.L. ch. 93A §§ 2, 11).

B. Each Claim Is Time-Barred

Seven of Plaintiff’s claims sound in tort: Count II (“Tortious Interference with Contractual Relations”); Count III (“Misappropriation of Trade Secrets”); Count IV (“Conversion”); Count V (“Unjust Enrichment”); Count VI (“Misrepresentation”); Count VII (“Negligent Misrepresentation”); and Count VIII (“Fraudulent Concealment”). Plaintiff also brings a claim under Mass. Gen. L. ch. 93A (Count X). Because the Complaint and documents incorporated therein leave no doubt that each is time-barred, Counts II, III, IV, V, VI, VII, VIII and X must be dismissed. *See, e.g., LaChapelle v. Berkshire Life Ins. Co.*, 142 F.3d 507, 509 (1st Cir. 1998) (“Granting a motion to dismiss based on a limitations defense is entirely appropriate when the pleader’s allegations leave no doubt that an asserted claim is time-barred.”).

In Massachusetts, the statute of limitations for tort claims is three years. Mass. Gen. L. ch. 260 § 2A. The statute of limitations for 93A claims is four years. Mass. Gen. L. ch. 260 § 5A. The limitations period begins to run when a claim accrues. *Id.* A claim accrues when “an

event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury.” *Bowen v. Eli Lilly & Co.*, 557 N.E.2d 739, 741 (Mass. 1990).

Over four years before he filed this lawsuit, Plaintiff was on notice of the same alleged injuries animating his tort and 93A claims. He said so himself. Plaintiff filed suit in the Massachusetts Superior Court on October 15, 2003. In letters he wrote to various Bard personnel dated October 10, 1999 and January 6, 2000, Plaintiff articulated a position virtually identical to that in his Complaint. Plaintiff references and relies upon those letters in his Complaint. *Id.* at ¶ 51 (“Several letters were written advising among others, Corporate Board Members, Engineering, Sales, Marketing and corporate legal staff that [Bard was] using [Plaintiff’s] technology and proprietary information without permission.”). Consequently, this Court may properly consider the contents thereof in deciding the instant motion to dismiss. *Beddall v. State St. Bank & Trust Co.*, 137 F.3d 12, 17 (1st Cir. 1998) (“When ... a complaint’s factual allegations are expressly linked to – and admittedly dependent upon – a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6).”). Bard retained Plaintiff’s letters, and attaches them hereto as Exhibits A, B, C and D.

The thrust of Plaintiff’s tort and 93A claims is that Bard stole Plaintiff’s trade secrets in the Bard Tigertail™ Ureteral Catheter, then secretly and without Plaintiff’s permission conveyed those trade secrets to another manufacturer – co-defendant Futuremed Interventional, Inc. (“Futuremed”). In fact, this allegation is as stale as it is patently untrue¹: Plaintiff has been

¹ The fact is, Plaintiff proved profoundly unable to manufacture the Tigertail™ product up to Bard’s specifications. There is abundant evidence of this. If Plaintiff created a proprietary process for manufacturing the device, it clearly did not work. The suggestion that Bard would have any interest in stealing a faulty manufacturing process and giving it to another supplier is absurd.

peddling the identical accusation for over four years. It has not availed him in his multiple attempts to squeeze a cash settlement out of Bard, and it must not avail him in his attempt to bring time-barred claims now.

On October 10, 1999, Plaintiff wrote a letter to Burt Mirsky, President of Bard Urological Division ("BUD"). In that letter, Plaintiff stated the following:

[I]t has been brought to my attention that Tigertail™ is still available through Bard Urology, which under the circumstances is confusing to me. We have not supplied BUD with product for about one year and therefore I have to wonder where additional inventory has come from [sic]. This letter is an attempt to ascertain this information because it has been established and is well defined that the BUD Tigertail™ technology and concept is the intellectual property of SME Design. Any second source manufacture utilizing SME Design technology which includes material and process information would have to be licensed from [sic] and approved by SME Design.

Exhibit A. Thus, Plaintiff was, by October 10, 1999, on notice that Bard had continued to sell the Tigertail™ product after Plaintiff stopped manufacturing it. Because, in Plaintiff's (erroneous) view, Bard could not outsource Tigertail™ manufacturing to another supplier without first obtaining a license and approval from Plaintiff, Plaintiff was indisputably on notice by October 10, 1999 that Bard may have caused him the very same injury upon which his tort and 93A claims are predicated.

In addition, in three letters sent by Plaintiff to various Bard personnel on January 6, 2000, Plaintiff set forth in detail the core of the factual allegations contained in the Complaint.² In a January 6, 2000 letter to Burt Mirsky (President, BUD), Plaintiff stated:

The issue is more and more complicated now that my Trade Secrets has [sic] been divulged and the Soft Tip product line is successful. Additionally, if these issues are not addressed, BUD will be violating patents I am drafting and clash with opportunities under negotiation with other organizations BUD has 30 days to respond with a significant proposal that will address this issue Contact me ... or this is my last communication and we will end up in court.

² Indeed, as he stated in his letters, Plaintiff had by January 6, 2000 already retained Gary Lambert -- the same attorney representing him in the case at bar.

Exhibit B (emphasis in original).

In a January 6, 2000 letter to Nadia Adler, Bard's Vice President, General Counsel and Secretary, Plaintiff stated:

In this case I'm sure you could be instrumental in eliminating one more BUD liability that sooner or later concerns the parent company I hope you can see this through to a speedy resolution. Otherwise I expect BUD to settle this with out [sic] further incident or we will end up in court.

Exhibit C (emphasis in original).

Finally, in a January 6, 2000 letter to Banks Neil, Bard in-house counsel, Plaintiff comprehensively described the factual basis for each of the tort claims and the 93A claim in the Complaint:

[I]f a reasonable offer is not presented to me with in [sic] 30 days, I will move forward with legal action BUD is *very* wrong All intellectual property related to Soft Tip Catheters such as materials specification and manufacturing processes are the property of SME, *not* BUD. I invented, developed and produced this product. I specified the material that provided significant soft tip radiopacity, and weld strength and presented it to BUD *Let me repeat*, it was *my* process and design and SME only sold bulk versions per BUD color specifications. BUD only has the right to the Trademark "Tigertail." BUD supported SME on a patent strategy where we were all in agreement that SME did not have to pursue a patent at this time At no time was there an issue of ownership of the technology, it was clearly SME's patent and technology Furthermore, BUD had a Confidentiality Agreement with SME. Accordingly, BUD has violated the terms of this agreement under the circumstances This technology is an asset of mine and I expect to continue to use it. BUD's use of my technology is with out [sic] consent and is impacting my ability to make a living. We will demand damages accordingly. Therefore I request BUD cease activities related to the sale or manufacturing of product related to SME technology until this issue is resolved This letter is being copied to my attorneys and I hope for a speedy close to this issue. Otherwise this is the last communication that will come directly from me until a court decision put [sic] this to rest.

Exhibit D (all emphasis in original).

As evidenced by the letters, Plaintiff was on notice by October 10, 1999³ that Bard may have caused him injury by permitting another manufacturer to produce the Tigertail™. The statute of limitations for his tort claims thus expired three years later, on October 10, 2002; for his 93A claim, the statute of limitations expired four years later, on October 10, 2003. Plaintiff filed suit in the Massachusetts Superior Court on October 15, 2003 – over a year too late for his seven tort claims and five days too late for his 93A claim. Although fraudulent concealment – Count VIII of Plaintiff’s Complaint – may toll the statute of limitations, there is no tolling once the Plaintiff has actual knowledge of the facts giving rise to his cause of action. *Demoulas v. Demoulas Super Markets, Inc.* 677 N.E.2d 159, 174 (Mass. 1997). Plaintiff’s letters unquestionably establish that he had such knowledge.

As a result, each of Plaintiff’s seven tort claims – Counts II – VIII, inclusive – and his 93A Claim – Count X – must be dismissed.

C. The Fraud-Based Claims Lack 9(b) Particularity

Three of Plaintiff’s claims sound in fraud: Count VI (“Misrepresentation”); Count VII (“Negligent Misrepresentation”); and Count VIII (“Fraudulent Concealment”). Because Plaintiff fails to state the circumstances constituting fraud with the particularity required by Fed.R.Civ.P. 9(b), Counts VI, VII and VIII must be dismissed. *See, e.g., Suna v. Bailey Corp.*, 107 F.3d 64, 71 (1st Cir. 1997) (“‘Because all of plaintiffs’ ... claims [were not pleaded with sufficient particularity], the district court properly dismissed these claims [under 12(b)(6)] for failure to meet Rule 9(b).’”) (quoting *Lucia v. Prospect St. High Income Portfolio*, 36 F.3d 170, 174 (1st Cir. 1994) (affirming trial court’s dismissal, on 12(b)(6) grounds, of fraud-related claims lacking the particularity required under 9(b)).

³ Even if the limitations period did not begin to run until January 6, 2000, all of Plaintiff’s tort claims would be time-barred, leaving just his 93A claim, which must be dismissed for the independent reasons discussed below in Section I.E.

Fed.R.Civ.P. 9(b) states that “[i]n all averments of fraud ..., the circumstances constituting fraud ... shall be stated with particularity.” The Rule plainly applies to Counts VI and VIII. *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (“Although state law governs the burden of proving fraud at trial, the procedure for pleading fraud in federal courts in all diversity suits is governed by the special pleading requirements of Federal Rule of Civil Procedure 9(b).”). *Accord Simcox v. San Juan Shipyard, Inc.*, 754 F.2d 430, 439 n.9 (1st. Cir. 1985). Moreover, this district has “clearly held that Rule 9(b) applies to claims of negligent misrepresentations.” *Lindner Dividend Fund v. Ernst & Young*, 880 F. Supp. 49, 57 (D. Mass. 1995). *Accord In re Stratus Computer, Inc. Sec. Litig.*, 1992 U.S. Dist. LEXIS 22481 (D. Mass. 1992) (Zobel, J.), *adopting* 1992 U.S. Dist. LEXIS 21587 (D. Mass. 1991); *Mosko v. DeFilippo*, 1991 U.S. Dist. LEXIS 13501, *6 (D. Mass. 1991) (Zobel, J.). Therefore, the heightened pleading requirements of Rule 9(b) apply to Counts VI, VII and VIII.

As to the degree of particularity required, the First Circuit “has strictly applied Rule 9(b).” *New England Data Services, Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987). “[T]he clear weight of authority is that Rule 9 requires specification of the time, place, and content of an alleged false representation Mere allegations of fraud, corruption or conspiracy, averments to conditions of mind, or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such accusations are repeated.” *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996) (citations omitted). *See also Hayduk*, 775 F.2d at 443 (“[9(b)] does not permit a complainant to file suit first, and subsequently to search for a cause of action.”); *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228 (1st Cir. 1980). “[A] complaint making [fraud-related] allegations must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the

statements were made, and (4) explain why the statements were fraudulent.” *Suna*, 107 F.3d at 68 (numbers in original) (citations omitted).

Each of Plaintiff’s three fraud-based claims fails to satisfy heightened pleading requirements of Rule 9(b) as specifically defined in *Suna*. First, in Count VI (“Misrepresentation”), Plaintiff claims that “Defendants” (he does not specify *which* of the three defendants) made three sets of “representations” – first “as to proper notification to the Food and Drug Administration pertaining to the BUD Soft Tip Catheter[,]” second “as to filing a Master Design History for their internal records[,]” third “as to resubmitting their 510k application to the FDA[.]” Complaint at ¶¶ 90-92. However, Plaintiff fails to satisfy a *single one* of the four elements of a well-pleaded fraud claim enunciated in *Suna*. He does not (1) specify the content of a single allegedly fraudulent statement made by Bard; (2) identify the speaker of any such statement; (3) state either where *or* when such statements were made; or (4) explain why such a statement could be considered fraudulent as to Plaintiff.

To be sure, although he lumps all three co-defendants together in Count VI, elsewhere in his Complaint Plaintiff seems to single out Bard as the speaker of these alleged misrepresentations. *See id.* at ¶ 27. Even giving Plaintiff the benefit of that supposition, however, Count VI still falls terribly short of satisfying the heightened pleading requirements of 9(b). That is, Plaintiff does not state with particularity the *contents* of Bard’s representations as to its “notification” to the FDA, filing a Master Design History or resubmitting its 510k application, let alone explain with particularity why those alleged representations were fraudulent *as to him*. It is one thing to claim that Bard made misrepresentations to the FDA – it is quite another to claim that Bard’s alleged misrepresentations to the FDA somehow defrauded *Plaintiff*. Plaintiff does not state with particularity how *he* was conceivably defrauded by

anything Bard did or did not tell the FDA. Neither does Plaintiff state with particularity when *or* where the alleged misrepresentations occurred. This, by itself, is fatal. *See Swartz v. Schering-Plough Corp.*, 53 F. Supp. 2d 95, 105 (D. Mass. 1999). Count VI must be dismissed.

Count VII (“Negligent Misrepresentation”) must suffer the same fate. In Count VII, Plaintiff makes the same factual allegations as in Count VI – that unspecified “Defendants” made unspecified “representations” as to “proper notification to the [FDA][,]” “filing a Master Design History[,],” and “resubmitting their 510k application[.]” Complaint at ¶¶ 101-103. The only difference between Count VI and Count VII is Plaintiff’s boilerplate recitation of the different elements of each tort – the former involving intentional conduct, the latter negligent conduct. As with Count VI, Count VII clearly must be dismissed.

Finally, Count VIII (“Fraudulent Concealment”) must be dismissed. In Count VIII, Plaintiff claims that unspecified Defendants (we will assume, *arguendo*, that Plaintiff means to single out Bard) “concealed and suppressed material facts” as to six things: (1) “notification to the [FDA] pertaining to the BUD Soft Tip Catheter”; (2) “filing a Master Design History for their internal records”; (3) “resubmitting the 510k to the FDA”; (4) “dissemination to third parties of Plaintiff’s technology, intellectual property and trade secrets”; (5) “use of the Plaintiff’s technology, intellectual property and trade secrets”; and (6) “use of the Plaintiff’s technology, intellectual property and trade secrets to apply for a patent.” Complaint at ¶¶ 111-116.

Despite this elaboration of various *categories* of concealed facts, Plaintiff fails to state with particularity the *contents* of the allegedly “material” facts, as he is required to do in the First Circuit. Not only does Plaintiff fail to state with particularity what the material facts *were*, he fails to explain with particularity why the alleged concealment of such facts was in any way

fraudulent *as to him*. Plaintiff does not state with particularity how *he* was conceivably defrauded by anything Bard did or did not tell the FDA. Plaintiff plainly fails to plead Count VIII with the heightened degree of particularity required by Rule 9(b). Accordingly, Count VIII – like Counts VI and VII – must be dismissed.

D. Count II Lacks A Necessary Element

Plaintiff claims that Bard intentionally interfered with his contractual relations, *see* Complaint at ¶¶ 71-75 (Count II), specifically by using “information gained from [Plaintiff] to contract directly with the same companies and entities that Epstein would have rightfully made contractual relationships with.” Complaint at ¶ 73. Because Plaintiff fails to allege that Bard interfered with a *single* contemplated contract or prospective business relationship, Count II must be dismissed.

Under Massachusetts law, a contemplated contract or prospective business relationship such as that which Plaintiff claims Bard prevented him from obtaining is called an “advantageous [business] relation.” *Buster v. George W. Moore, Inc.*, 783 N.E.2d 399, 414 n.22 (Mass. 2003).

The specific elements which must be proved to establish intentional interference with advantageous business relations are: (1) a business relationship or contemplated contract of economic benefit; (2) the defendant’s knowledge of such relationship [or contract]; (3) the defendant’s intentional and malicious interference with it; [and] (4) the plaintiff’s loss of advantage directly resulting from the defendant’s conduct.

ELM Medical Lab. v. RKO Gen., 532 N.E.2d 675, 681 (Mass. 1989) (citation omitted).

In his Complaint, Plaintiff fails to allege that Bard interfered with any “business relationship or contemplated contract of economic benefit.” Quite the opposite – Plaintiff claims that he “entered into a written agreement with Cook Urology to provide a Ureteral Stent based on the same technology that was used to design and produce the Ureteral Catheter

[Plaintiff] provided to [Bard].” Complaint at ¶ 34. Plaintiff claims that “Cook Urological has expressed an interest in [Plaintiff’s] licensing and producing medical devices based upon his technology[,]” and that Boston Scientific has a “desire to have several meetings.” Complaint at ¶ 62. Whatever Plaintiff claims Bard to have done, he does not allege facts showing that Bard interfered with *any* of his alleged advantageous business relations. As a result, Count II must be dismissed for failure to state a claim upon which relief may be granted.

E. Count X Lacks A Necessary Element

Plaintiff claims that Bard violated Mass. Gen. L. ch. 93A §§ 2 and 11, and requests relief accordingly. *See* Complaint at ¶¶ 126-130 (Count X). Because Plaintiff fails to allege that the center of gravity of the circumstances that give rise to his 93A claim was primarily and substantially in Massachusetts, Count X must be dismissed.

Mass. Gen. L. ch. 93A § 11 limits the scope of 93A:

No action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred *primarily* and *substantially* within the commonwealth.

Id. (emphasis supplied). Under this provision, the critical inquiry is “whether the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth.” *Kuwaiti Danish Computer Co. v. Digital Equip. Corp.*, 781 N.E.2d 787, 799 (Mass. 2003). Adhering to the SJC’s *Kuwaiti Danish* test, as a federal court must, *Kenda Corp. v. Pot O’Gold Money Leagues, Inc.*, 329 F.3d 216, 235 (1st Cir. 2003) (“[W]e must follow the SJC’s pronouncements on interpretations of Massachusetts statutes[]”), the First Circuit recently held that a 93A claim must fail where the “pivotal events underlying [the] 93A claim” occurred outside of Massachusetts, even if a “number of activities” occurred in Massachusetts as a result thereof. *Id.* at 235-36.

According to the Complaint – the accuracy of which is, of course, disputed – the pivotal event underlying Plaintiff’s 93A claim occurred when “Gary Teague [then an employee in BUD’s Covington offices] and or [sic] BUD caused the disclosure of [Plaintiff’s] technology to a third party, [Futuremed].” Complaint at ¶ 37. Perhaps to underscore the central importance of the allegation, Plaintiff repeats it in paragraph 50: “[Bard] ... without the express permission of [Plaintiff] ... conveyed [Plaintiff’s] specifications and corresponding proprietary information to Future[m]ed.” Without an unauthorized transfer of his proprietary information from BUD to Futuremed, Plaintiff clearly has no 93A claim. This is so because, absent such wrongdoing, there was, *ipso facto*, no breach of contract (Count I), no tortious interference with contractual relations (Count II), no misappropriation of trade secrets (Count III), no conversion (Count IV), no unjust enrichment (Count V), no fraudulent concealment as to the unauthorized transfer (Count VIII) and no breach of the implied covenant of good faith and fair dealing (Count IX). The pivotal event underlying Plaintiff’s 93A claim is clearly the alleged unauthorized transfer of Plaintiff’s proprietary information from BUD to Futuremed.

Plaintiff fails to allege that the pivotal event underlying his 93A claim occurred in Massachusetts. Plaintiff claims that Futuremed is located in Athens, Texas, Complaint at ¶ 4, and that BUD – the Bard division allegedly responsible for the unauthorized disclosure – is located in Covington, Georgia. Complaint at ¶ 3. Plaintiff (correctly) does not allege that either Futuremed or BUD either has an office in Massachusetts, or that the alleged unauthorized transfer occurred in Massachusetts. Therefore, it is plain on the face of the Complaint that the pivotal event underlying Plaintiff’s 93A claim – had it happened at all – would have occurred in Texas, Georgia or some other unspecified location. In any event, Plaintiff fails to allege that the pivotal event giving rise to his 93A claim occurred in Massachusetts. Under no reading of the

Complaint can it be inferred that the center of gravity of the circumstances giving rise to Plaintiff's 93A claim was primarily and substantially in Massachusetts. Fact-findings on this issue would be futile. As a result, Count X must be dismissed for failure to state a claim upon which relief can be granted.

II. Counts VI, VII And VIII Are Pre-Empted

In Counts VI, VII and VIII, Plaintiff alleges that "Defendants" (we will assume, *arguendo*, that Plaintiff means to single out Bard) made various "representations" to the Food and Drug Administration ("FDA"), which representations were "false." *See* Complaint at ¶¶ 90-99, 101-109, 111-120. Plaintiff goes on to claim that he was injured by those representations, though he fails to explain why or how Bard's representations to the FDA conceivably had anything to do with him. It is unclear from his Complaint whether Plaintiff claims to have relied on false representations made by Bard to the FDA, by Bard to Plaintiff *about* representations Bard supposedly made to the FDA, or some combination thereof. It is clear, however, that to the extent Counts VI, VII and VIII advance a "fraud-on-the-FDA" theory, they must be dismissed because, as a matter of law, those claims are impliedly pre-empted by federal law. *Adames v. Exec. Airlines, Inc.*, 258 F.3d 7, 16 (1st Cir. 2001) (affirming district court dismissal of pre-empted claim for lack of subject matter jurisdiction).

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law[.]" *id.* at 348, which federal law is the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, 21 U.S.C. § 301 (1994 ed. and Supp. IV). Per *Buckman*, where a plaintiff's state-law fraud claims "exist solely by virtue of the FDCA disclosure requirements[.]" *id.* at 353, those

claims must be dismissed.

The policy rationale animating *Buckman* is substantial:

State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA.

Id. at 350.

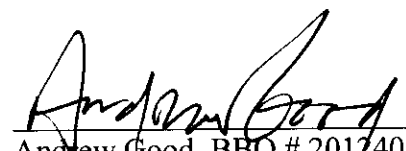
In his Complaint, Plaintiff repeatedly cites the FDCA as the source of the requirement that Bard make various disclosures to the FDA. *See* Complaint at ¶¶ 26, 30, 31. Though his allegations are far from clear, Plaintiff appears to claim in Counts VI, VII and VIII that Bard's disclosures to the FDA were either false or incomplete. These are matters which, according to *Buckman*, must be left to the FDA – not individual state-law tort suits. The FDCA, as amended by the MDA, pre-empts Plaintiff's state-law tort claims against Bard which arise from Bard's allegedly false or deficient FDA-mandated disclosures. As a result, Counts VI, VII and VIII – to the extent they advance “fraud-on-the-FDA” allegations – must be dismissed for lack of subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, Counts II, III, IV, V, VI, VII, VIII and X of the Complaint should be dismissed.

DATED: December 29, 2003

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Andrew Good", is written over a horizontal line.

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